

San José State University
College of Engineering
Department of Biomedical Engineering

BME 188, Biomedical Device Manufacturing, Fall 2022, 3 units

Course and Contact Information

Instructor:	Herbert Bellucci
Office Location:	On-line, via Zoom
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Email:	herbert.bellucci@sjsu.edu
Office Hours:	Friday 1:30-2:30pm (by appointment)
Class Days/Time:	Friday 3:00-5:45pm
Classroom:	On-line, via Zoom
Prerequisites:	BME 25, MATE 25, BME 115, BME 177, all with grade of C- or better

Course Description

Overview of manufacturing processes for producing biomedical devices, implants, instruments, prosthetics, and capital equipment. Introduction to design processes and tools that facilitate start-up and expansion of manufacturing activities.

The goals of most biomedical device engineering development projects are, first, to prove the efficacy and safety of the proposed device, and soon thereafter, to manufacture the product consistently and economically, and in adequate quantity, to maximize its benefits to the intended patient population. This course is oriented to students interested in designing and developing manufacturable biomedical devices, such as single-use procedure devices and implants, reusable surgical instruments, prosthetics, medical optics and visualization systems, as well as medical capital equipment, electronics, and software-based products. The student will be introduced to approaches to the design process and related tools which facilitate initiation and scale-up of manufacturing activities. The course provides an overview of biomedical device manufacturing processes, such as machining, forming, molding, and assembly. Included in the course activities are hands-on lab exercises and virtual visits to biomedical manufacturing operations.

Course Format

Technology Intensive Online Course

In Fall Semester 2022, this course is offered exclusively via an online (synchronous) delivery format, and as such requires Internet connectivity via an electronic device capable of presenting PowerPoint slides and video presentations accompanied with audio teaching commentary. Students are required to have an electronic device (laptop, desktop or tablet) with a display, a camera, and built-in microphone, capable of interactive two-way communication via Zoom conferencing software. See the [Zoom Help Center](#) for additional information on using Zoom. SJSU has a free [equipment loan](#) program available for students.

Students are responsible for ensuring that they have access to reliable Internet connectivity during class sessions and tests. If students are unable to have reliable Internet connection, they must inform the instructor, as soon as possible to determine an alternative. See [Learn Anywhere](#) website for current Wi-Fi connectivity options on campus.

Faculty Web Page and MYSJSU Messaging

Course materials such as syllabus, handouts, notes, assignment instructions, etc. can be found on the Canvas Learning Management System course login website at <http://sjsu.instructure.com>. You are responsible for regularly checking with the messaging system through MySJSU on Spartan App Portal (<http://one.sjsu.edu>), or other communication system as indicated by the instructor, to learn of any updates. For help with using Canvas see Canvas Student Resources (<https://www.sjsu.edu/ecampus/software-tools/teaching-tools/canvas/student-resources>).

Course Learning Outcomes (CLO)

Upon successful completion of this course, students will be able to:

1. Identify and select appropriate materials for use in manufacturing biomedical device designs.
2. Clearly relate design requirements to potential suppliers (internal and external).
3. Evaluate design alternatives and recommend sensible strategies for manufacturing of newly-designed biomedical device components and sub-assemblies.
4. Describe the importance of Design For Manufacturability (DFM) review and risk analysis of biomedical device designs.
5. Plan for start-up of manufacturing for a wide range of biomedical device products.

Required Texts/Readings

Textbook:

- Kalpakjian, S. & Schmid, S., Manufacturing Engineering and Technology, 8th Edition

Other Readings:

- FDA Good Manufacturing Practices (21 CFR 820), U.S. Government Publishing Office

Other technology requirements:

- SolidWorks Student Edition (recommended)

Library Liaison for Biomedical Engineering

Anamika Megwalu

Phone: (408) 808-2089

Email: anamika.megwalu@sjsu.edu

Course Requirements and Assignments

Success in this course is based on the expectation that students will spend, for each unit of credit, a minimum of 45 hours over the length of the course (normally three hours per unit per week) for instruction, preparation/studying, or course related activities, including but not limited to internships, labs, and clinical practica. Other course structures will have equivalent workload expectations as described in the syllabus.

More details about student workload can be found in University Syllabus Policy S16-9 at <http://www.sjsu.edu/senate/docs/S16-9.pdf>.

Attainment of the learning objectives (as listed above) will be assessed via class activities, assignments, home works, in-class quizzes, one mid-term examination, a final examination and a term paper.

Assignments

Assignments will be handed out from time to time, and must be submitted on the due date. No late assignments will be accepted.

Quizzes

Several quizzes consisting of short sets of questions to demonstrate comprehension of recent lesson material from lectures, assigned readings, and other class activities will be administered during the semester. Typically, these will be held at the beginning of class. There will be no make-up opportunities for missed quizzes or tardy arrival. However, the lowest Quiz grade will be dropped from the course grade computation, mainly to account for unavoidable class absence or tardiness.

Term paper

All students are required to write a term paper, individually, on research advancements of a particular manufacturing process, digested from published research articles. More specific requirements will be defined in documentation to be distributed separately in class.

The deadline for submitting the term paper will be during the last week of the semester, prior to the Final Exam (see the Course Schedule, attached).

The term paper must be word processed electronically, and be in accordance with the Biomedical Engineering Department's Thesis Guidelines. The term paper must be submitted by electronic copy, in MS Word format. **The electronic copy must be one file, and should be identical to any hard copy that is submitted. Submitted papers may be checked by turnitin.com for plagiarism.**

Please note that **all deadlines will be strictly adhered to.**

NOTE that University Policy F15-12 on Attendance and Participation at <http://www.sjsu.edu/senate/docs/F15-12.pdf> states that "Attendance shall not be used as a criterion for grading.", but also states that "Students are expected to attend all meetings for the courses in which they are enrolled as they are responsible for material discussed therein, and active participation is frequently essential to ensure maximum benefit to all class members". Some discretion is given under University Policy F15-12 for instructors to grade for attendance, in that "Participation may be used as a criterion for grading when the parameters and their evaluation are clearly defined in the course syllabus and the percentage of the overall grade is stated". However, there will be no specific Attendance and Participation grading criteria for BME 188, although class attendance and active participation in class discussions are strongly encouraged.

Final Examination or Evaluation

There will be one mid-term examination, and one final examination. Each examination will cover the entire course material covered until the time of the examination, subject to further communication in class and on Canvas. The date of the mid-term examinations is indicated in the Course Schedule, attached herein, and subject to change as communicated in class and on Canvas. The final examination will be held according to the university's final examination schedule. There will be no make-up examinations.

Grading Information

Course letter grade will be determined per the following table, based upon the weighted sum of numerical grades for all assignments and examinations (rounded to the nearest integer):

A+	97% and above
A	93% - 96%
A-	90% - 92%
B+	87% - 89%
B	83% - 86%
B-	80% - 82%
C+	77% - 79%
C	73% - 76%
C-	70% - 72%
D+	67% - 69%
D	63% - 66%
D-	60% - 62%
F	59% and below

Numerical grades will be awarded for all assignments and examinations, and will be weighted to determine course grade as shown below (rounded to the nearest integer):

Midterm	25%
Final Examination	25%
Assignments	15%
Quizzes	15%
Term Paper	20%

Late assignments will be only be accepted via prior approval by the Instructor. Absence during examinations and quizzes without prior approval will result in a zero grade for that test. Prior approval will be given only under exceptional circumstances.

Extra credit assignments may be given, at the sole discretion of the instructor.

Note that “All students have the right, within a reasonable time, to know their academic scores, to review their grade-dependent work, and to be provided with explanations for the determination of their course grades.” See University Policy F13-1 at <http://www.sjsu.edu/senate/docs/F13-1.pdf> for more details.

Class Session Protocol

Attendance and arrival times

Students are expected to be set up for lecture via Zoom Conference prior to the scheduled time for the class session. Attendance in class is not mandatory and shall not be used, per se, as a criterion for grading. However, class attendance and participation are highly recommended.

Behavior

Students should remain respectful of each other at all times. Interruptive or disruptive attitudes are discouraged. While in the class session the use of electronic devices (laptops, tablets, smartphones) should be limited to activities related to the learning objectives, and should not be used for personal communication, included

messaging and use of social media. Cell phones and other electronics must be silenced prior to entering the class session. Microphones used for two-way communication in Zoom conferences should be muted if/when background noise would be audible to the class.

Assignments

Each assignment that is submitted must be individually prepared by each student, unless specified to be submitted as a team assignment.

Safety

When using University facilities, students should familiarize themselves with all emergency exits and evacuation plans. When departing buildings in the evening, students should be aware of their surroundings, and carry a cell phone.

University Policies

Per University Policy S16-9, university-wide policy information relevant to all courses, such as academic integrity, accommodations, etc., will be available on the Office of Graduate and Undergraduate Programs Syllabus Information web page at <http://www.sjsu.edu/gup/syllabusinfo/>

Use of Webcams and Microphones in Class

To promote student engagement and participation in the class experience, it is the Instructor's preference that students turn on their webcams during Zoom class sessions. However, the use of student's camera and microphone is voluntary, and students wishing to maintain privacy may opt to leave their cameras and/or microphone off. Due to the generally large class size, student microphones will normally be muted, except during discussion or questions, to avoid unexpected disruptions of the class.

Recording of Zoom Classes

Zoom class sessions will be recorded and posted to Canvas for the use of registered students, solely for the purpose of studying course materials. Students are permitted only to view the class recordings via Canvas, and not to download class videos or PowerPoint slides. Students are not permitted to share class recordings with anyone not enrolled in the class, nor are students permitted to make or distribute their own recordings by any electronic means, unless by specific prior permission of the Instructor. Class recordings are the sole property of the Instructor, are protected by Instructor's copyright, and will be deleted following the end of the semester.

As the use of student webcams and microphones during class is voluntary, such voluntary use will serve as consent under University policy ([S12-7](#)), which requires consent from all individuals who appear in a class recording. Any student that needs accommodations or assistive technology due to a disability should work with the [Accessible Education Center \(AEC\)](#), and the instructor.

Instructor may, at their sole discretion, monitor/proctor online exams (Quizzes, Mid-Term, and Final Exam) utilizing University-supported proctoring software, based on course objectives. Please note it is the instructor's discretion to determine the method of proctoring, subject to approval by the University. Instructor may require the use of webcams during exams for the purpose of proctoring. In some cases, remote proctoring software may be incompatible with AEC accommodation. Please consult with the [AEC](#) staff for more information.

[Best practices](#) for academic integrity in online courses are available on the [Teach Anywhere](#) site on eCampus.

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Tentative Course Schedule

(Subject to change with fair notice)

2022 Dates	Session #	Topic
Fri 8/19/22	1A	Introduction, Goals, Overview
	1B	Product Design Process
Fri 8/26/22	2A	Regulatory Environment (FDA, ISO), Quality Systems
	2B	Design Controls, Documentation
Fri 9/2/22	3A	Design For Manufacturability (DFM), Risk Management
	3B	Biomedical materials: Metals
Fri 9/9/22	4A	Casting, forging [QUIZ #1]
	4B	Metal extrusion, drawing
Fri 9/16/22	5A	Forming processes: stamping, bending
	5B	Conventional Machining
Fri 9/23/22	6A	Abrasive Machining, Grinding
	6B	Advanced Machining
Fri 9/30/22	7A	Biomedical Materials: Plastics [QUIZ #2]
	7B	Plastic Extrusion, Injection Molding; Mid-Term Review
Fri 10/7/22	8	MID-TERM TEST (via Zoom & Canvas)
Fri 10/14/22	9A	RIM, Structural foam, Thermoforming
	9B	Biomedical Materials: Ceramics, Glass;
Fri 10/21/22	10A	Rapid prototyping, additive mfg., nanoscale mfg.
	10B	Assembly processes: fastening, welding, bonding
Fri 10/28/22	11	Guest Speaker: Sterilization Methods
Fri 11/4/22	12A	Single-use Devices, Cleanroom assembly, Packaging
	12B	Reusable Devices
Thu 11/10/22	13A	Electronics, Software [QUIZ #3]
(Rescheduled)	13B	Medical Capital Equipment
Fri 11/18/22	14A	Manufacturing Control Systems
	14B	Mfg. Facilities, Continuous Improvement Methods
Fri 11/25/22		Thanksgiving Holiday -- NO CLASS
Fri 12/2/22	15A	Mfg./Supply Chain Management; Contract Mfrs [QUIZ #4]
	15B	Final Exam Review
Thu 12/8/22		FINAL EXAM @ 12:15pm - 2:30pm (via Zoom & Canvas)